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22 **BARBARA FRISBY**

23 **UNITED STATES DISTRICT COURT**
24 **SOUTHERN DISTRICT OF CALIFORNIA**

25 **BARBARA FRISBY**

26 Plaintiff,

27 v.

28 **AMYLIN PHARMACEUTICALS,
INC., AMYLIN
PHARMACEUTICALS, LLC,
ELI LILLY AND COMPANY, and
DOES 1-100,**

Defendants.

No. 13-cv-2483 AJB MDD

**PLAINTIFF'S COMPLAINT
FOR DAMAGES**

JURY TRIAL DEMANDED

1 COMES NOW Plaintiff and complains and alleges against Defendants,
2 Does 1 through 100, and each of them as follows:

3 **GENERAL ALLEGATIONS**

4 1. Plaintiff, Barbara Frisby (“Plaintiff”), by and through her
5 undersigned attorneys, brings this action for personal injuries suffered as a
6 proximate result of being prescribed and ingesting the defective and
7 unreasonably dangerous prescription drug Byetta (exenatide synthetic) (the
8 “Drug” or “Byetta”), a prescription medication used to help lower blood sugar
9 levels in adults with diabetes mellitus type 2, which at all times relevant hereto,
10 was manufactured, designed, tested, packaged, labeled, marketed, advertised,
11 distributed, and sold by Defendants Amylin Pharmaceuticals, Inc., Amylin
12 Pharmaceuticals, LLC, Eli Lilly and Company (collectively, the “Amylin Lilly
13 Defendants”), and Does 1 through 100 (collectively, the “Doe Defendants”) (the
14 Amylin Lilly Defendants and the Doe Defendants collectively are the
15 “Defendants”).

16 2. The true names or capacities whether individual, corporate or
17 otherwise, of the Doe Defendants 1 through 100, inclusive, are unknown to Plaintiff
18 who therefore, pursuant to California *Code of Civil Procedure* §474, sues said
19 Defendants by such fictitious names. Plaintiff believes and alleges that each of the
20 Defendants designated herein by fictitious names is in some manner legally
21 responsible for the events and happenings herein referred to and caused damages
22 proximately and foreseeably to Plaintiff and/or Plaintiff as alleged herein.

23 3. At all times herein mentioned, each of the Amylin Lilly Defendants
24 was the agent, servant, partner, aider and abettor, co-conspirator, and joint venturer
25 of each of the remaining Amylin Lilly Defendants herein and were at all times
26 operating and acting within the purpose and scope of said agency, service,
27 employment, partnership, conspiracy and joint venture and rendered substantial
28 assistance and encouragement to the other Amylin Lilly Defendants, knowing that

1 their conduct constituted a breach of duty.

2 4. At all times herein mentioned, each of the Doe Defendants was the
3 agent, servant, partner, aider and abettor, co-conspirator, and joint venturer of each
4 of the remaining Doe Defendants / Amylin Lilly Defendants herein and were at all
5 times operating and acting within the purpose and scope of said agency, service,
6 employment, partnership, conspiracy and joint venture and rendered substantial
7 assistance and encouragement to the other Doe Defendants / Amylin Lilly
8 Defendants, knowing that their conduct constituted a breach of duty.

9 5. There exists, and at all times herein mentioned, there existed, a unity of
10 interest in ownership between certain Defendants and other certain Defendants
11 such that any individuality and separateness between the certain Defendants has
12 ceased and these Defendants are the alter ego of the other certain Defendants, and
13 exerted control over those Defendants. Adherence to the fiction of the separate
14 existence of these certain Defendants as any entity distinct from other certain
15 Defendants will permit an abuse of the corporate privilege and would sanction
16 fraud and would promote injustice.

17 6. The injuries and damages to Plaintiff and/or Plaintiff were caused by
18 the wrongful acts, omissions, and fraudulent representations of Defendants, many
19 of which occurred within the State of California.

20 7. At all times herein mentioned, Defendants were each engaged in the
21 business of, or were successors in interest to, entities engaged in the business of
22 research, designing, formulating, compounding, testing, manufacturing, producing,
23 processing, assembling, inspecting, distributing, marketing, labeling, promoting,
24 packaging and/or advertising for sale or selling the Drug.

25 8. At all times herein mentioned Defendants were each authorized to do
26 or otherwise engaged in business within the State of California and did in fact
27 supply the aforementioned products within the State of California and elsewhere.

28 9. At all times herein mentioned, the officers and directors of Defendants

1 authorized and directed the production and promotion of the Drug when they knew,
2 or with the exercise of reasonable care should have known, of the hazards and
3 dangerous propensities of the Drug, and thereby actively participated in the tortious
4 conduct which resulted in the physical injuries described herein.

5 **JURISDICTION AND VENUE**

6 10. Plaintiff is informed and believes, and thereon alleges that at all times
7 herein mentioned each of the Defendants hereto are individuals, corporations,
8 partnerships and/or unincorporated associations organized and existing under and
9 by virtue of the laws of the State of California, or the laws of some other state or
10 foreign jurisdiction, and that said Defendants, and each of them, were and are
11 authorized to do and are doing business in the State of California, or the laws of
12 some other state or foreign jurisdiction, including Defendant Amylin
13 Pharmaceuticals, Inc., which maintains its corporate headquarters in California,
14 and that said Defendants have and do regularly conduct business in the County of
15 San Diego, State of California.

16 11. Venue is proper in this county because at least one Defendant, Amylin
17 Pharmaceuticals, Inc., has its principal place of business in this county.

18 **PLAINTIFF**

19 12. Plaintiff Barbara Frisby is a natural person currently residing in Osage
20 City, Kansas. Plaintiff was a resident of Osage City, KS at the time she ingested
21 the Drug and was diagnosed with thyroid cancer.

22 13. Plaintiff was prescribed and used the Drug beginning in or around
23 2005 until on or about May 2012. On or about October 16, 2011, Plaintiff suffered
24 severe physical, economic and emotional injuries as a result of said Drug,
25 including but not limited to Plaintiff being diagnosed with thyroid cancer. Plaintiff
26 was unaware that her injuries were caused by the Drug until within two years of
27 the filing of this complaint.

28 **DEFENDANTS**

1 19. According to the American Diabetes Association, “Type 2 diabetes is
2 the most common form of diabetes. Millions of Americans have been diagnosed
3 with type 2 diabetes. [...] In type 2 diabetes, either the body does not produce
4 enough insulin or the cells ignore the insulin. Insulin is necessary for the body to
5 be able to use glucose for energy. When you eat food, the body breaks down all
6 of the sugars and starches into glucose, which is the basic fuel for the cells in the
7 body. Insulin takes the sugar from the blood into the cells. When glucose builds
8 up in the blood instead of going into cells, it can lead to diabetes complications.”¹

9 20. Type 2 diabetes mellitus is a chronic disease, characterized by insulin
10 resistance and deficient insulin secretion leading to high blood sugar levels or
11 ‘hyperglycemia’, which is the hallmark of the condition.

12 21. Diabetes remains the most frequent cause of blindness, amputations
13 and dialysis worldwide.² With the current estimate of more than 350 million
14 patients worldwide³ it is considered to be one of the major health challenges of
15 the 21st century.

16 22. Byetta is supposed to help prevent these diabetic complications.

17 23. Two of the most recently approved classes of therapeutic agents for
18 the treatment of type 2 diabetes, glucagon-like peptide-1 (GLP-1) receptor (GLP-
19 1R) agonists (such as Byetta) and dipeptidyl peptidase-4 (DPP-4) inhibitors (such
20 as Januvia), exert their actions through potentiation of incretin receptor signaling.
21 Incretins are gut-derived hormones, principally GLP-1 and glucose-dependent
22 insulinotropic peptide (GIP), that are secreted at low basal levels in the fasting
23 state.

24 24. Byetta was approved by the FDA in April of 2005 and was marketed
25 to the medical community and general public shortly thereafter.

26 1. <http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-type2>

27 2. *Id.*

28 3. IDF Diabetes atlas, <http://www.idf.org/diabetesatlas/5e/diabetes>.

1 25. Byetta is a member of the new class of Drug known as glucagon-like
2 peptide-1 (GLP-1) receptor agonists.

3 26. Defendants have results from a carcinogenicity rat study with once-
4 weekly Exenatide that demonstrates a statistically significant association between
5 Exenatide once-weekly and thyroid c-cell tumors.

6 27. Defendants have not included information regarding the
7 carcinogenicity rat study with Exenatide once-weekly in their Byetta label.

8 28. Defendants also have results from a human epidemiologic study of
9 Byetta that demonstrate a statistically significant increased risk for thyroid
10 cancer.

11 29. Defendants have not included information regarding increased risk
12 for thyroid cancer demonstrated by their epidemiologic study in their Byetta
13 label.

14 30. Due to the flawed formulation of Byetta, it increases the risk of
15 thyroid cancer in those diabetic patients to whom it is prescribed.

16 31. Defendants concealed their knowledge that Byetta can cause life-
17 threatening, thyroid cancer from Plaintiff, other consumers, the general public,
18 and the medical community. Indeed, the manufacturer of Byetta never even
19 mentioned 'thyroid cancer' in their Drug's product inserts.

20 32. The other GLP-1 receptor agonist drug, Victoza, in the same class of
21 drugs as Byetta, carries a black box warning for thyroid cancer in its label.

22 33. Specifically, the Defendants did not adequately inform consumers
23 and the prescribing medical community about the risks of thyroid cancer
24 associated with Byetta usage, nor did Defendants warn or otherwise advise
25 physicians to institute monitoring procedures looking for the first signs of
26 changes within the thyroid or identifying and addressing risk in patients with a
27 personal or family history of thyroid cancer.

28 34. The current warnings for the Drug are simply inadequate. The

1 Defendants have failed and continue to fail in their duties to warn and protect the
2 consuming public, including the Plaintiff herein.

3 35. Even if the warnings were sufficient, which Plaintiff strongly denies,
4 Byetta still lacks any benefit sufficient to tolerate the extreme risk posed by the
5 ingestion of the Drug. Other drugs to treat diabetes are available. Byetta is quite
6 simply too dangerous and defective as formulated. The Defendants should
7 withdraw Byetta from the market.

8 36. Defendants willfully, wantonly, and with malice withheld the
9 knowledge of increased risk of thyroid cancer in users of Byetta to prevent any
10 chances of their product's registration being delayed or rejected by FDA.

11 37. As the manufacturers and distributors of Byetta, Defendants knew or
12 should have known that the Drug's usage was associated with thyroid cancer.

13 38. With the knowledge of the true relationship between use of Byetta
14 and thyroid cancer, rather than taking steps to pull the Drug off the market or
15 provide strong warnings, Defendants promoted and continue to promote Byetta
16 as safe and effective treatments for adults with type 2 diabetes.

17 39. Byetta is one of the top selling drugs in the country.

18 40. In 2010, the worldwide sales of Byetta reached \$0.710 billion and
19 visiongain predicts sales to reach \$1.00 billion by 2015 and \$1.28 billion by
20 2021.⁴

21 41. While Defendants have enjoyed great financial success from their
22 blockbuster Drug, they continue to place American citizens at risk of developing
23 deadly thyroid cancer.

24 42. Consumers, including Plaintiff, who have used Byetta for the
25 treatment of their type 2 diabetes had several alternative safer products available
26 to treat their condition and have not been adequately warned about the significant

27 _____
28 4. www.pipelinereview.com/store/toc/sample_pages_vg0151.pdf.

1 risks and lack of benefits associated with Byetta therapy.

2 43. Defendants, through their affirmative misrepresentations and
3 omissions, actively concealed from Plaintiff and Plaintiff's physicians the true
4 and significant risks associated with Byetta use.

5 44. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians
6 were unaware, and could not have reasonably known or have learned through
7 reasonable diligence, that Plaintiff would be exposed to the risks identified in this
8 Complaint. The increased risks and subsequent medical damages associated with
9 Plaintiff's Byetta use were the direct and proximate result of Defendants'
10 conduct.

11 45. At all times relevant hereto, the Defendants have directly marketed
12 and distributed the Drug to the medical community.

13 46. At all times relevant hereto, the Defendants have directly marketed
14 the Drug to the consuming public throughout the United States, including the
15 Plaintiff, herein.

16 47. Defendants departed from and failed to meet requirements of laws,
17 regulations and class and product specific requirements including failing to
18 undertake adequate post approval marketing studies on safety of the Drug as
19 dictated by good pharmaceutical science standards.

20 48. Defendants both over-promoted the Drug and under-warned about its
21 risks, including:

- 22 a. in print advertising;
- 23 b. on their websites and blogs;
- 24 c. advertised to users that use of the Drug was "safe" whereas it was not
25 and Defendants knew or should have know it was not; and
- 26 d. promoted the Drug to doctors, clinics and users as safer than (or as
27 safe as) other diabetes drugs.

1 49. Defendants did not perform adequate safety testing on the Drug as
2 required by good pharmaceutical science practice.

3 50. Defendants failed to provide proper and full information as to the
4 safety of the Drug.

5 51. Defendants failed to ensure that full and correct safety labeling and
6 warnings were used in pharmacy sheets that accompanied the Drug to the
7 purchaser.

8 52. Defendants have never sought to enlarge their warnings to include a
9 warning about thyroid cancer risks associated with the use of the Drug.

10 53. Instead, Defendants marketed (and continue to market) the Drug as
11 having a low risk of side effects and continue to minimize (or conceal) the
12 Drug's deadly side effects.

13 54. Manufacturers such as the Defendants, herein, are required to have
14 systems in place to collect and analyze any complaints they receive from doctors
15 and hospitals about their products.

16 55. Defendants did not timely apprise the F.D.A., the public, nor treating
17 physicians of the defect(s) in Defendants' Drug, despite Defendants' knowledge
18 that injuries had occurred and had been reported to Defendants due to the above-
19 described defects.

20 56. At all times mentioned herein, Defendants knew, or in the exercise of
21 reasonable care should have known, that the Drug was of such a nature that it
22 was not properly designed, manufactured, tested, inspected, packaged, labeled,
23 distributed, marketed, examined, sold, supplied, prepared, and/or provided with
24 proper warnings, was not suitable for the purpose it was intended and was
25 unreasonably likely to injure the product's users.

26 57. Plaintiff and Plaintiff's prescribing health care providers were
27 unaware of the true degree and incidence of thyroid cancer associated with the
28 use of the Drug and would have used and prescribed other methods for diabetes

1 control if they had been so informed.

2 58. Plaintiff suffered from severe and personal injuries, which were
3 permanent and lasting in nature, physical pain, and mental anguish, including
4 diminished enjoyment of life, as well as the need for medical treatment,
5 monitoring and/or medications.

6 59. As a direct and proximate result of the aforesaid conduct of Defendants
7 and each of them as set forth hereinafter, Plaintiff suffered injuries, including but
8 not limited to thyroid cancer, and damages in a sum in excess of the jurisdictional
9 limits of the Court.

10 60. As a direct and proximate result of the aforesaid conduct of the
11 Defendants, and each of them, Plaintiff was compelled to incur obligations for
12 physicians, surgeons, nurses, hospital care, medicine, hospices, x-rays, medical
13 supplies, and other medical treatment, the true and exact amount thereof being
14 unknown to Plaintiff at this time, and Plaintiff prays leave to amend this complaint
15 accordingly when the true and exact cost thereof is ascertained.

16 61. As a further direct and proximate result of the said conduct of the
17 Defendants, and each of them, Plaintiff suffered a loss of income, wages, profits
18 and commissions, a diminishment of earning potential, and other pecuniary losses,
19 the full nature and extent of which are not yet known to Plaintiff; and leave is
20 requested to amend this complaint to conform to proof at the time of trial.

21 62. By reasons of the premises, Plaintiff has been caused great pain and
22 suffering.

23 **STATEMENT OF PLAINTIFF'S INJURIES**

24 63. In or around 2005, Plaintiff was prescribed and began taking Byetta
25 upon the direction of Plaintiff's physician for maintenance of Type II diabetes.

26 64. Subsequently, and as a direct result of the ingestion of Byetta, the
27 Plaintiff was diagnosed with thyroid cancer on or about October 16, 2011. Had
28 Plaintiff and/or Plaintiff's physician been properly warned by Defendants

1 regarding the risk of thyroid cancer from usage of this prescription medication,
2 Plaintiff's physician would not have prescribed Byetta and Plaintiff would never
3 have ingested this prescription medication.

4 65. As a direct result of being prescribed Byetta for this period of time,
5 Plaintiff was permanently and severely injured, having suffered serious
6 consequences from Plaintiff's Byetta usage, including but not limited to, the
7 development of thyroid cancer.

8 66. Plaintiff, as a direct and proximate result of Plaintiff's Byetta use,
9 suffered severe mental and physical pain and suffering, along with economic
10 loss.

11 67. As a proximate result of Defendants' acts and omissions, Plaintiff
12 suffered the injuries described hereinabove due to Plaintiff's ingestion of Byetta.
13 Plaintiff accordingly seeks damages associated with these injuries for the losses
14 suffered by the Plaintiff.

15 68. Plaintiff would not have used Byetta had Defendants properly
16 disclosed the risks associated with the Drug's use.

17 **FIRST CAUSE OF ACTION**

18 **STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

19 (As to All Defendants)

20 69. Plaintiff hereby incorporates by reference all paragraphs of this
21 Complaint as if fully set forth herein and further alleges as follows:

22 70. Defendants are liable under the theory of strict products liability.
23 Defendants were at all times relevant to this suit, and are now, engaged in the
24 business of designing, manufacturing, testing, marketing, and placing into the
25 stream of commerce pharmaceuticals for sale to, and use by, members of the
26 public, including the Byetta at issue in this lawsuit. The Byetta manufactured by
27 Defendants reached Plaintiff without substantial changes and was ingested as
28 directed. The Drug was defective and unreasonably dangerous when it entered

1 into the stream of commerce and when used by Plaintiff.

2 71. The Plaintiff was administered the Drug for its intended purposes.

3 72. The Plaintiff could not have discovered any defect in the Drug
4 through the exercise of care.

5 73. Defendants, as manufacturers of pharmaceutical products, including
6 the Drug, are held to the level of knowledge of an expert in the field, and further,
7 Defendants knew or should have known that warnings and other clinically
8 relevant information and data which they distributed regarding the risks of
9 injuries and death associated with the use of Byetta were incomplete and
10 inadequate, if not intentionally void of critical information about Byetta's deadly
11 side effects.

12 74. Plaintiff did not have the same knowledge as Defendants and no
13 adequate warning or other clinically relevant information and data was
14 communicated to Plaintiff or to Plaintiff's treating physicians. The warnings that
15 were given by the Defendants were not accurate, clear, and/or were ambiguous or
16 incomplete.

17 75. Defendants had a continuing duty to provide consumers, including
18 Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant
19 information and data regarding the risks and dangers associated with the Drug, as
20 it became or could have become available to Defendants.

21 76. Defendants marketed, promoted, distributed and sold the
22 unreasonably dangerous and defective prescription drug, Byetta, to health care
23 providers empowered to prescribe and dispense the Drug to consumers, including
24 Plaintiff, without adequate warnings and other clinically relevant information and
25 data. Through both omission and affirmative misstatements, if not intentional
26 concealment, Defendants misled the medical community about the risk and
27 benefit balance of the Drug, which resulted in the Plaintiff's injury.

28 77. Despite the fact that Defendants knew or should have known that the

1 Drug caused unreasonable and dangerous side effects, they continued to promote
2 and market the Drug without stating that there existed safer and more or equally
3 effective alternative drug products and/or providing adequate clinically relevant
4 information and data.

5 78. Defendants knew or should have known that consumers, Plaintiff
6 specifically, would foreseeably and needlessly suffer injury as a result of
7 Defendants' failures.

8 79. Defendants failed to provide timely and adequate warnings to
9 physicians, pharmacies, and consumers, including Plaintiff and to Plaintiff's
10 intermediary physicians, in at least the following ways:

- 11 a. Defendants failed to include adequate warnings and/or provide
12 adequate clinically relevant information and data that would alert
13 Plaintiff and Plaintiff's physicians to the dangerous risks of the Drug
14 including, among other things, its tendency to increase the risk of,
15 and/or cause, the development of thyroid cancer;
- 16 b. Defendants failed to provide adequate post-marketing warnings and
17 instructions after the Defendants knew or should have known of the
18 significant risks of, among other things, thyroid cancer; and
- 19 c. Defendants continued to aggressively promote and sell the Drug even
20 after they knew or should have known of the unreasonable risks of
21 developing thyroid cancer from ingestion of the Drug.

22 80. Defendants had an obligation to provide Plaintiff and Plaintiff's
23 physicians with adequate clinically relevant information and data and warnings
24 regarding the adverse health risks associated with exposure to the Drug, and/or
25 that there existed safer and more or equally effective alternative drug products.

26 81. By failing to provide Plaintiff and Plaintiff's physicians with
27 adequate clinically relevant information and data and warnings regarding the
28 adverse health risks associated with exposure to the Drug, and/or that there

1 existed safer and more or equally effective alternative drug products, Defendants
2 breached their duty of reasonable care and safety.

3 82. Defendants' actions described above were performed willfully,
4 intentionally, and with reckless disregard of the life and safety of the Plaintiff and
5 the public.

6 83. Defendants' actions described above violated the federal and state
7 Food, Drug and Cosmetic Acts and rendered the Drug misbranded.

8 84. As a direct and proximate result of the actions and inactions of the
9 Defendants as set forth above, Plaintiff was exposed to the Drug and suffered the
10 injuries and damages set forth hereinabove.

11 WHEREFORE, Plaintiff prays for judgment against Defendants as
12 hereinafter set forth.

13 **SECOND CAUSE OF ACTION**

14 **NEGLIGENCE**

15 (As to All Defendants)

16 85. Plaintiff hereby incorporates by reference all paragraphs of this
17 Complaint as if fully set forth herein and further allege as follows:

18 86. Defendants had a duty to exercise reasonable care in the
19 manufacture, sale and/or distribution of the Drug into the stream of commerce,
20 including a duty to assure that the product did not cause users to suffer from
21 unreasonable, dangerous side effects.

22 87. Defendants failed to exercise ordinary care in the manufacture, sale,
23 testing, quality assurance, quality control, and/or distribution of the Drug into
24 interstate commerce in that Defendants knew or should have known that the Drug
25 created a high risk of unreasonable, dangerous side effects, including causing and
26 increasing the risk of developing thyroid cancer.

27 88. Defendants were negligent in the design, manufacture, testing,
28 advertising, warning, marketing and sale of the Drug.

1 dangerous propensities when put to its intended use and would cause severe
2 injury (or death) to the user. The Drug was unaccompanied by adequate
3 warnings of its dangerous propensities that were either known or reasonably
4 scientifically knowable at the time of distribution.

5 97. As a proximate and legal result of the defective and unreasonably
6 dangerous condition of the Drug manufactured and supplied by Defendants,
7 Plaintiff was caused to suffer the herein described injuries and damages.

8 98. After Plaintiff was made aware or otherwise came to believe that the
9 injuries discussed herein were a result of the Drug, notice was duly given to
10 Defendants of the breach of said warranty.

11 WHEREFORE, Plaintiff prays for judgment against Defendants as
12 hereinafter set forth.

13 **FOURTH CAUSE OF ACTION**
14 **BREACH OF EXPRESS WARRANTY**

15 (As to All Defendants)

16 99. Plaintiff hereby incorporates by reference all paragraphs of this
17 Complaint as if fully set forth herein and further alleges as follows:

18 100. The aforementioned manufacturing, compounding, packaging,
19 designing, distributing, testing, constructing, fabricating, analyzing,
20 recommending, merchandizing, advertising, promoting, supplying and selling of
21 the Drug was expressly warranted to be safe for use by Plaintiff, and other
22 members of the general public.

23 101. At the time of the making of the express warranties, Defendants had
24 knowledge of the purpose for which the Drug was to be used and warranted the
25 same to be in all respects, fit, safe, and effective and proper for such purpose.
26 The Drug was unaccompanied by adequate warnings of its dangerous
27 propensities that was either known or knowable at the time of distribution.

28 102. Plaintiff and Plaintiff's physicians reasonably relied upon the skill

1 and judgment of Defendants, and upon said express warranty, in using the Drug.
2 The warranty and representations were untrue in that the product was unsafe and,
3 therefore, unsuited for the use for which it was intended. The Drug could and did
4 thereby cause Plaintiff to suffer the herein described injuries and damages.

5 103. As soon as the true nature of the product and the fact that the
6 warranty and representations were false was ascertained, Defendants were
7 notified of the breach of said warranty.

8 WHEREFORE, Plaintiff prays for judgment against Defendants as
9 hereinafter set forth.

10 **FIFTH CAUSE OF ACTION**

11 **DECEIT BY CONCEALMENT – Cal. Civ. Code §§ 1709, 1710**

12 (As to All Defendants)

13 104. Plaintiff hereby incorporates by reference all paragraphs of this
14 Complaint as if fully set forth herein and further alleges as follows:

15 105. California *Civil Code* section 1709 provides that one, who willfully
16 deceives another with intent to induce him to alter his position to his injury or
17 risk, is liable for any damages that he thereby suffers.

18 106. California *Civil Code* section 1710 provides, in part, that a deceit,
19 within the meaning of section 1709, is the suggestion, as a fact, of that which is
20 not true, by one who does not believe it to be true; the assertion, as a fact, of that
21 which is not true, by one who has no reasonable ground for believing it to be
22 true; or the suppression of fact, by one who is found to disclose it, or who gives
23 information of other facts which are likely to mislead for want of communication
24 of that fact.

25 107. The Defendants, and each of them, from the time that the Drug was
26 first tested, studied, researched, evaluated, endorsed, manufactured, marketed and
27 distributed, and up to the present, willfully deceived the Plaintiff, Plaintiff's
28 prescribing physicians and healthcare providers, the medical, scientific,

1 pharmaceutical and healthcare communities, and the public in general, by
2 suggesting to some or all of them untrue facts about their product that they did
3 not believe to be true or had no reasonable ground for believing them to be true,
4 and by concealing from them the true facts concerning the Drug, which the
5 Defendants had a duty to disclose.

6 108. At the time the Drug was manufactured, distributed, and sold to
7 Plaintiff, the Defendants were in a unique position of knowledge, which was not
8 possessed by Plaintiff or Plaintiff's physicians, concerning the safety and
9 effectiveness of the Drug, and thereby held a position of superiority over Plaintiff
10 and Plaintiff's physicians.

11 109. Through their unique knowledge and expertise regarding the
12 defective nature of the Drug, and through their marketing statements to
13 physicians and patients in advertisements, promotional materials, labels and other
14 communications as herein alleged, Defendants professed to Plaintiff's physicians
15 that they were in possession of facts demonstrating that the Drug was safe and
16 effective for its intended use and was not defective, when in fact it was not, and
17 in fact Defendants possessed information they did not disclose that they had a
18 duty to disclose to ensure such physicians were not misled.

19 110. Defendants knew or had no reasonable ground to believe the truth of
20 their representations to Plaintiff's physicians. Such representations were made to
21 induce the purchase of the Drug, and Plaintiff and Plaintiff's physicians relied
22 upon those statements when purchasing and administering the Drug.

23 111. Defendants took unconscionable advantage of their dominant
24 position of knowledge with regard to Plaintiff and Plaintiff's physicians and
25 engaged in constructive fraud in their relationship.

26 112. Plaintiff and Plaintiff's physicians reasonably relied on these
27 misrepresentations and misleading facts.

28 113. The Defendants intentionally concealed and suppressed the true facts

1 concerning the Drug with the intent to defraud the Plaintiff, Plaintiff's
2 prescribing physicians and healthcare providers, the medical, scientific,
3 pharmaceutical and healthcare communities, and the public in general, in that
4 Defendants knew that the physicians and healthcare providers would not have
5 prescribed the Drug, and Plaintiff would not have used the Drug if Plaintiff had
6 known the true facts concerning the dangers of the Drug.

7 114. As a result of the foregoing fraudulent and deceitful conduct by
8 Defendants, and each of them, Plaintiff was caused to suffer the herein described
9 injuries and damages.

10 WHEREFORE, Plaintiff prays for judgment against Defendants as
11 hereinafter set forth.

12 **SIXTH CAUSE OF ACTION**
13 **NEGLIGENT MISREPRESENTATION**

14 (As to All Defendants)

15 115. Plaintiff hereby incorporates by reference all paragraphs of this
16 Complaint as if fully set forth herein and further alleges as follows:

17 116. Defendants owed a duty in all of their several undertakings,
18 including the communication of information concerning the Drug, to exercise
19 reasonable care to ensure that they did not, in those undertakings, create
20 unreasonable risks of personal injury to others.

21 117. Defendants disseminated information to physicians concerning the
22 properties and effects of the Drug, with the intent and expectation that physicians
23 would rely on that information in their decisions regarding the prescribing of
24 drug therapy for their patients.

25 118. Alternatively or in addition, when Defendants disseminated
26 information to physicians concerning the properties and effects of the Drug, they
27 should have realized, in the exercise of due care to avoid causing personal injury
28 to others, that physicians would reasonably rely on that information in their

1 decisions concerning the prescription of drug therapy for their patients.

2 119. By uniformly honored custom and practice, the label for a
3 prescription drug product, whether name brand or generic, as it is distributed to
4 pharmacies for dispensing to patients, per the prescriptions of their physicians,
5 accompanies or is placed on or in the package from which the drug is to be
6 dispensed.

7 120. A drug company will generally distribute to physicians the labels for
8 a name brand prescription drug product along with samples of the product, when
9 it is being introduced to the market, and disseminate the content of the labels
10 (i.e., the product labeling) to physicians through publication of the drug's
11 monograph in the PDR, and otherwise communicate information regarding the
12 drug through advertising, distribution of promotional materials, sales
13 presentations by company sales representatives, group sales presentations, and
14 sponsored publications and seminar speakers.

15 121. Defendants disseminated false information, as referenced above, to
16 physicians and the medical community and to their patients with knowledge that
17 the information was false or in conscious disregard of its truth or falsity.

18 122. Defendants disseminated the false information, as referenced above,
19 to physicians, the medical community and their patients with the intention to
20 deceive physicians and their patients and to induce the physicians to prescribe the
21 Drug.

22 123. Alternatively, or in addition, Defendants failed to exercise reasonable
23 care to ensure that the information disseminated to physicians concerning the
24 properties and effects of the Drug were accurate and not misleading, Defendants
25 failed to exercise reasonable care to insure that accurate and not misleading
26 information was disseminated to physicians concerning the properties and effects
27 of the Drug by failing to publish or disseminate current and accurate information.

28 124. Defendants expected or should have expected that patients taking the

1 Drug, pursuant to prescriptions written or issued in reliance on false information,
2 would be placed in unnecessary, avoidable, and unreasonable danger due to
3 unwarranted exposure to the Drug.

4 125. As a proximate and foreseeable result of this dissemination to
5 physicians, by Defendants consciously or negligently disseminating false
6 information, the Plaintiff suffered grievous bodily injury, and consequent
7 economic and other loss, as described above, when Plaintiff's physicians, in
8 reasonable reliance upon the negligently inaccurate, misleading and otherwise
9 false information disseminated by the Defendants, and reasonably but
10 unjustifiably believing the information to be true, prescribed for the Plaintiff the
11 Drug.

12 126. As a result of the foregoing negligent misrepresentations by
13 Defendants, and each of them, the Plaintiff was caused to suffer the herein
14 described injuries and damages.

15 WHEREFORE, Plaintiff prays for judgment against Defendants as
16 hereinafter set forth.

17 **SEVENTH CAUSE OF ACTION**

18 **FRAUD BY CONCEALMENT**

19 (As to All Defendants)

20 127. Plaintiff hereby incorporates by reference all paragraphs of this
21 Complaint as if fully set forth herein and further alleges as follows:

22 128. At all times mentioned in this Complaint, Defendants had the duty
23 and obligation to disclose to Plaintiff and to Plaintiff's physicians, the true facts
24 concerning the Drug, that is, that the Drug was dangerous and defective, and
25 likely to cause serious health consequences to users, including the injuries as
26 described in this Complaint.

27 129. Defendants concealed important facts from Plaintiff and from
28 Plaintiff's physicians and healthcare providers which facts include, but are not

1 limited to, the fact that Defendants:

- 2 a. Failed to disclose any information related to a connection between
- 3 use of the Drug and the development of thyroid cancer;
- 4 b. Did not inform prescribers and users of studies related to use of the
- 5 Drug and the development of thyroid cancer, and
- 6 c. Concealed from prescribers and users that numerous adverse events
- 7 have been reported linking use of the Drug to thyroid cancer.

8 130. At all times mentioned in this Complaint, Defendants made
9 affirmative representations to Plaintiff and Plaintiff's prescribing physicians prior
10 to the day the Drug was first prescribed to Plaintiff that the Drug was safe as set
11 forth above while concealing the material facts set forth herein.

12 131. At all times mentioned in this Complaint, Defendants had the duty
13 and obligation to disclose to Plaintiff and to Plaintiff's physicians and healthcare
14 providers the true facts concerning the Drug, which facts include, but are not
15 limited to, the fact that the Drug was dangerous and likely to cause serious health
16 consequences to users, including death.

17 132. At all times mentioned in this Complaint, Defendants intentionally,
18 willfully, and maliciously concealed or suppressed the facts set forth above from
19 Plaintiff's physicians, and therefore from Plaintiff, with the intent to defraud as
20 alleged herein.

21 133. At all times mentioned in this Complaint, neither Plaintiff nor
22 Plaintiff's physicians or healthcare providers were aware of the concealed facts
23 set forth herein. Had they been aware of those facts, they would not have acted as
24 they did, that is, that the Drug would not have been prescribed as part of
25 Plaintiff's treatment and Plaintiff would not have been injured as a result.

26 134. Had Plaintiff been informed of the deaths and serious injury adverse
27 reports associated with the Drug's usage, Plaintiff would have immediately
28 discontinued the Drug or never taken the Drug in the first instance.

- 1 a. Representing that the Drug is safe, fit, and effective for human use,
2 knowing that said representations were false, and concealing that the
3 Drug has a serious propensity to cause injuries to users;
- 4 b. Engaging in advertising programs designed to create the image,
5 impression and belief by consumers and physicians that the Drug is
6 safer than other diabetes treatments, even though the Defendants
7 knew this to be false, and even though the Defendants had no
8 reasonable grounds to believe this to be true;
- 9 c. Purposely downplaying and understating the health hazards and risks
10 associated with the Drug;
- 11 d. Issuing promotional literature and commercials deceiving potential
12 users of the Drug by relaying positive information, including
13 testimonials from satisfied users, and manipulating statistics to
14 suggest widespread acceptability and safety, while downplaying the
15 known adverse and serious health effects and concealing material
16 relevant information regarding the safety and efficacy of the Drug;
- 17 e. Engaging in a practice undertaking unlawful, unfair, or fraudulent
18 acts by refraining from taking any action that would provide
19 prescribing physicians with appropriate information and protect
20 patients who use their products, including Plaintiff, such as failing to
21 engage in proper pharmacovigilance, signal detection, and follow up,
22 review of the literature, regulatory review, updating labels, and
23 timely and properly implementing label changes and conducting
24 proper research, tests, and studies to ensure the continued safety of
25 the Drug, and taking appropriate action to disseminate to prescribing
26 physicians and healthcare providers appropriate and permitted
27 product information and labels concerning safety issues and safe
28 prescribing practices for the Drug.

1 disseminating untrue and misleading statements as defined by *Business &*
2 *Professions Code* § 17500 by engaging in the following acts and practices with
3 intent to induce members of the public to purchase and use Defendants' Byetta
4 products:

- 5 a. Representing that the Drug was safe, fit, and effective for human use,
6 knowing that said representations were false, and concealing that the
7 Drug had a serious propensity to cause injuries to users;
- 8 b. Engaging in advertising programs designed to create the image,
9 impression and belief by consumers and physicians that the Drug was
10 safer than other diabetes drugs, even though the Defendants knew
11 this to be false, and even though the Defendants had no reasonable
12 grounds to believe this to be true;
- 13 c. Purposely downplaying and understating the health hazards and risks
14 associated with the Drug;
- 15 d. Issuing promotional literature and commercials deceiving potential
16 users of the Drug by relaying positive information, including
17 testimonials from satisfied users, and manipulating statistics to
18 suggest widespread acceptability and safety, while downplaying the
19 known adverse and serious health effects and concealing material
20 relevant information regarding the safety and efficacy of the Drug;
21 and
- 22 e. Engaging in a practice undertaking unlawful, unfair, or fraudulent
23 acts by refraining from taking any action that would provide
24 prescribing physicians with appropriate information and protect
25 patients who use the Drug, including Plaintiff, such as failing to
26 engage in proper pharmacovigilance, signal detection and follow up,
27 review of the literature, regulatory review, updating labels and timely
28 and properly implementing label changes and conducting proper

1 research, tests and studies to ensure the continued safety of the Drug,
2 and taking appropriate action to disseminate to prescribing
3 physicians and healthcare providers appropriate and permitted
4 product information and labels concerning safety issues and safe
5 prescribing practices for the Drug.

6 149. The foregoing practices constitute false and misleading advertising
7 within the meaning of *Business & Professions Code* § 17500.

8 150. The acts of untrue and misleading statements by Defendants
9 described herein above present a continuing threat to members of the public in
10 that the acts alleged herein are continuous and ongoing, and the public will
11 continue to suffer the harm alleged herein.

12 151. As a result of their conduct described above, Defendants have been
13 and will be unjustly enriched. Specifically, Defendants have been unjustly
14 enriched by receipt of hundreds of millions of dollars in ill-gotten gains from the
15 sale and prescription of the Drug in California, sold in large part as a result of the
16 acts and omissions described herein.

17 152. Pursuant to *Business & Professions Code* § 17535, Plaintiff seeks an
18 order of this court compelling the Defendants to provide restitution and
19 injunctive relief calling for Defendants, and each of them, to cease unfair
20 business practices in the future.

21 153. Plaintiff seeks restitution of the monies collected by Defendants, and
22 each of them, and other injunctive relief to cease such false and misleading
23 advertising in the future.

24 WHEREFORE, Plaintiff prays for judgment against Defendants as
25 hereinafter set forth.

26
27 **TENTH CAUSE OF ACTION**
28 **VIOLATIONS of Cal. Civ. Code § 1750**

1 (As to All Defendants)

2 154. Plaintiff hereby incorporates by reference all paragraphs of this
3 Complaint as if fully set forth herein and further alleges as follows:

4 155. Plaintiff is informed and believes and thereon alleges that
5 Defendants, and each of them, by the acts and misconduct alleged herein,
6 violated the Consumers Legal Remedies Act, California *Civil Code* §§ 1750 et.
7 seq. ("CLRA").

8 156. Plaintiff hereby seeks injunctive relief as appropriate against
9 Defendants, and each of them, for their violations of *Civil Code* §§ 1750 et. seq.
10 The CLRA applies to Defendants' actions and conduct described herein because
11 it extends to transactions which are intended to result, or which have resulted, in
12 the sale of goods to consumers.

13 157. Plaintiff was a "consumer" within the meaning of *Civil Code* §
14 176l(d).

15 158. Defendants have violated, and continue to violate, the CLRA in
16 representing that goods have characteristics and benefits which they do not have,
17 in violation of *Civil Code* § 1770(a)(5).

18 159. At all times herein alleged Defendants have committed acts of
19 disseminating untrue and misleading statements as defined by *Civil Code* § 1770,
20 by engaging in the following acts and practices with intent to induce members of
21 the public to purchase and use the Drug:

- 22 a. Representing that the Drug is safe, fit, and effective for human use,
23 knowing that said representations were false, and concealing that the
24 Drug had a serious propensity to cause injuries to users;
- 25 b. Engaging in advertising programs designed to create the image,
26 impression and belief by consumers and physicians that the Drug is
27 safer than other diabetes medications, even though the Defendants
28 knew this to be false, and even though the Defendants had no

1 reasonable grounds to believe this to be true;

- 2 c. Purposely downplaying and understating the health hazards and risks
3 associated with the Drug;
- 4 d. Issuing promotional literature and commercials deceiving potential
5 users of the Drug by relaying positive information, including
6 testimonials from satisfied users, and manipulating statistics to
7 suggest widespread acceptability or safety, while downplaying the
8 known adverse and serious health effects and concealing material
9 relevant information regarding the safety and efficacy of the Drug;
10 and
- 11 e. Engaging in a practice undertaking unlawful, unfair or fraudulent
12 acts by refraining from taking any action that would provide
13 prescribing physicians with appropriate information and protect
14 patients who use their products, including Plaintiff, such as failing to
15 engage in proper pharmacovigilance, signal detection and follow up,
16 review of the literature, regulatory review, updating labels and timely
17 and properly implementing label changes and conducting proper
18 research, tests and studies to ensure the continued safety of the Drug,
19 and taking appropriate action to disseminate to prescribing
20 physicians and healthcare providers appropriate and permitted
21 product information and labels concerning safety issues and safe
22 prescribing practices for the Drug.

23 160. The foregoing practices constitute false and misleading advertising
24 and representations within the meaning of *Civil Code* § 1770. The acts of untrue
25 and misleading statements by Defendants described herein present a continuing
26 threat to members of the public and individual consumers in that the acts alleged
27 herein are continuous and ongoing, and the public and individual consumers will
28 continue to suffer harm as alleged herein. Unless Defendants are enjoined from

1 continuing to engage in these violations of the CLRA, Plaintiff and other
2 consumers will continue to be harmed by the wrongful actions and conduct of
3 Defendants. Pursuant to California *Civil Code* § 1780, Plaintiff seeks an order of
4 this court for injunctive relief calling for Defendants, and each of them, to cease
5 such deceptive business practices in the future.

6 WHEREFORE, Plaintiff prays for judgment against Defendants as
7 hereinafter set forth.

8 **PUNITIVE DAMAGES ALLEGATIONS**

9 (As to All Defendants)

10 161. Plaintiff hereby incorporates by reference all preceding paragraphs as
11 if fully set forth herein.

12 162. Although Defendants knew or recklessly disregarded the fact that the
13 Drugs cause debilitating and potentially lethal side effects, Defendants continued
14 to market the Drugs to consumers, including Plaintiff, without disclosing these
15 side effects when there were safer alternative methods for treating type 2
16 diabetes.

17 163. Defendants knew of the Drugs' defective nature, as set forth herein,
18 but continued to design, manufacture, market, and sell them so as to maximize
19 sales and profits at the expense of the health and safety of the public, including
20 Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused
21 by the Drugs.

22 164. Defendants intentionally concealed or recklessly failed to disclose to
23 the public, including Plaintiff, the potentially life-threatening side effects of the
24 Drugs to ensure their continued and increased sales. Defendants failed to provide
25 warnings that would have dissuaded physicians from prescribing the Drugs and
26 consumers from purchasing and consuming the Drugs, thus depriving physicians
27 and consumers from weighing the true risks against the benefits of prescribing
28 and/or purchasing and consuming the Drugs.

1 5. For pre-judgment and post-judgment interest as followed by the laws
2 of the state of California;

3 6. Costs of suit incurred herein; and

4 7. For such other and further relief as the court may deem just and
5 proper.

6 **AS TO THE THIRD CAUSE OF ACTION FOR BREACH OF**
7 **IMPLIED WARRANTY:**

8 1. General damages according to proof at the time of trial;

9 2. Medical and other special damages, past, present and future,
10 according to proof at the time of trial;

11 3. Loss of earnings and loss of earnings capacity, according to proof at
12 the time of trial;

13 4. For medical monitoring according to proof;

14 5. For pre-judgment and post-judgment interest as followed by the laws
15 of the state of California;

16 6. Costs of suit incurred herein; and

17 7. For such other and further relief as the court may deem just and
18 proper.

19 **AS TO THE FOURTH CAUSE OF ACTION FOR BREACH OF**
20 **EXPRESS WARRANTY:**

21 1. General damages according to proof at the time of trial;

22 2. Medical and other special damages, past, present and future,
23 according to proof at the time of trial;

24 3. Loss of earnings and loss of earnings capacity, according to proof
25 at the time of trial;

26 4. For medical monitoring according to proof;

27 5. For pre-judgment and post-judgment interest as followed by the
28 laws of the state of California;

 6. Costs of suit incurred herein; and

1 7. For such other and further relief as the court may deem just and
2 proper.

3 **AS TO THE FIFTH CAUSE OF ACTION FOR DECEIT BY**
4 **CONCEALMENT IN VIOLATION OF *CIVIL CODE* §§ 1709, 1710:**

- 5 1. General damages according to proof at the time of trial;
- 6 2. Medical and other special damages, past, present and future,
7 according to proof at the time of trial;
- 8 3. Loss of earnings and loss of earnings capacity, according to proof at
9 the time of trial;
- 10 4. For medical monitoring according to proof;
- 11 5. For pre-judgment and post-judgment interest as followed by the laws
12 of the state of California;
- 13 6. Punitive and exemplary damages;
- 14 7. Costs of suit incurred herein; and
- 15 8. For such other and further relief as the court may deem just and
16 proper.

17 **AS TO THE SIXTH CAUSE OF ACTION FOR NEGLIGENT**
18 **MISREPRESENTATION:**

- 19 1. General damages according to proof at the time of trial;
- 20 2. Medical and other special damages, past, present and future,
21 according to proof at the time of trial;
- 22 3. Loss of earnings and loss of earnings capacity, according to proof
23 at the time of trial;
- 24 4. For medical monitoring according to proof;
- 25 5. For pre-judgment and post-judgment interest as followed by the
26 laws of the state of California;
- 27 6. Costs of suit incurred herein; and
- 28 7. For such other and further relief as the court may deem just and
proper.

1 **AS TO THE SEVENTH CAUSE OF ACTION FOR FRAUDULENT**
2 **CONCEALMENT:**

- 3 1. General damages according to proof at the time of trial;
- 4 2. Medical and other special damages, past, present and future,
5 according to proof at the time of trial;
- 6 3. Loss of earnings and loss of earnings capacity, according to proof
7 at the time of trial;
- 8 4. For medical monitoring according to proof;
- 9 5. For pre-judgment and post-judgment interest as followed by the
10 laws of the state of California;
- 11 6. Punitive and exemplary damages;
- 12 7. Costs of suit incurred herein; and
- 13 8. For such other and further relief as the court may deem just and
14 proper.

15 **AS TO THE EIGHTH CAUSE OF ACTION FOR VIOLATION OF**
16 ***BUSINESS AND PROFESSIONS CODE §§ 17200, et seq.:***

- 17 1. For injunctive relief, forever enjoining defendants from the acts of
18 unfair competition and untrue and misleading business practices, and ordering
19 defendants to pay restitution to Plaintiffs all funds acquired by means of any act
20 or practice declared by this Court to be in violation of *Business and Professions*
21 *Code §§ 17200, et seq.*, unlawful or fraudulent, or to constitute unfair competition
22 or untrue or misleading advertising;
- 23 2. For disgorgement of Defendants' profits;
- 24 3. For exemplary and punitive damages in an amount to be proven at
25 trial;
- 26 4. For attorneys' fees, according to proof;
- 27 5. For such other and further relief as the Court deems just and proper.

28 **AS TO THE NINTH CAUSE OF ACTION FOR VIOLATION OF**
BUSINESS AND PROFESSIONS CODE §§ 17500, et seq.:

1 1. For injunctive relief, forever enjoining defendants from the acts of
2 unfair competition and untrue and misleading business practices, and ordering
3 defendants to pay restitution to Plaintiffs all funds acquired by means of any
4 act or practice declared by this Court to be in violation of *Business and*
5 *Professions Code* §§ 17500, et seq., unlawful or fraudulent, or to constitute
6 unfair competition or untrue or misleading advertising;

7 2. For disgorgement of Defendants' profits;

8 3. For exemplary and punitive damages in an amount to be proven at
9 trial;

10 4. For attorneys' fees, according to proof;

11 5. For such other and further relief as the Court deems just and
12 proper.

13 **AS TO THE TENTH CAUSE OF ACTION FOR VIOLATION OF**
14 ***CIVIL CODE* §§ 1750, et seq.:**

15 1. For injunctive relief, forever enjoining defendants from the acts of
16 unfair competition and untrue and misleading business practices, and ordering
17 defendants to pay restitution to Plaintiffs all funds acquired by means of any
18 act or practice declared by this Court to be in violation of *Civil Code* §§ 1750,
19 *et seq.*, unlawful or fraudulent, or to constitute unfair competition or untrue or
20 misleading advertising;

21 2. For disgorgement of Defendants' profits;

22 3. For exemplary and punitive damages in an amount to be proven at
23 trial;

24 4. For attorneys' fees, according to proof;

25 5. For such other and further relief as the Court deems just and
26 proper.

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JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: December 13, 2013 Respectfully submitted,

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